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From the INTERNATIONAL SEARCHING AUTHORITY	PCT					
UNITED STATES OF AMERICA	NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION  FEB 2 4 2004 (PCT Rule 44.1)  RANGAXY P. DEPARTMENT					
	Date of mailing (day/month/year) 23/02/2004					
Applicant's or agent's file reference  RLL-299WO	FOR FURTHER ACTION See paragraphs 1 and 4 below					
International application No. PCT/IB 03/04845	International filing date (day/month/year) 30/10/2003					
Applicant RANBAXY LABORATORIES LIMITED						
The applicant is hereby notified that the International Search Report has been established and is transmitted herewith.  Filing of amendments and statement under Article 19: The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):  When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.  Where? Directly to the International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Fascimile No.: (41–22) 740.14.35  For more detailed instructions, see the notes on the accompanying sheet.						
The applicant is hereby notified that no International Search Article 17(2)(a) to that effect is transmitted herewith.  With regard to the protest against payment of (an) addition the protest together with the decision thereon has been applicant's request to forward the texts of both the protest.	nal fee(s) under Rule 40.2, the applicant is notified that:  transmitted to the International Bureau together with the est and the decision thereon to the designated Offices.					
no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.  4. Further action(s): The applicant is reminded of the following:  Shortly after 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the						
priority claim, must reach the International Bureau as provided in completion of the technical preparations for international publicated.  Within 19 months from the priority date, a demand for international wishes to postpone the entry into the national phase until 30 months.  Within 20 months from the priority date, the applicant must perform before all designated Offices which have not been elected in the priority date or could not be elected because they are not bound.	n Rules 90 <i>bis</i> .1 and 90 <i>bis</i> .3, respectively, before the tion.  If preliminary examination must be filed if the applicant of the from the priority date (in some Offices even later).  If the prescribed acts for entry into the national phase of demand or in a later election within 19 months from the					
Name and mailing address of the International Searching Authority	Authorized officer					

European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016

Margarita Tzelepi



These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

#### INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

#### What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

#### When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

#### Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been is filed, see below.

#### How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

### What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new:
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

# The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

- [Where originally there were 48 claims and after amendment of some claims there are 51]:
   "Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
- [Where originally there were 15 claims and after amendment of all claims there are 11]: "Claims 1 to 15 replaced by amended claims 1 to 11."
- [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
   "Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
  - "Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or "Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
- 4. [Where various kinds of amendments are made]: "Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

#### "Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

### It must be in the language in which the international appplication is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

### Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the International Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a), first sentence).

### Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.

Notes to Form PCT/ISA/220 (second sheet) (January 1994)



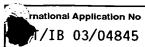
### INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference  RLL-299WO	FOR FURTHER see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.				
International application No.	International filing date (day	/month/year)	(Earliest) Priority (	Date (day/month/year)	
PCT/IB 03/04845	30/10/2	003	31	/10/2002	
Applicant RANBAXY LABORATORIES LIMIT	red				
This International Search Report has been according to Article 18. A copy is being tra	n prepared by this Internationa ansmitted to the International I	al Searching Auth Bureau.	ority and is transmitt	ed to the applicant	
	of a total of3 a copy of each prior art docur		report.		
Basis of the report     a. With regard to the language, the language in which it was filed, unli	international search was carri ess otherwise indicated under	ed out on the bas this item.	is of the internationa	application in the	
the international search w Authority (Rule 23.1(b)).	as carried out on the basis of	a translation of th	e international applic	cation furnished to this	
b. With regard to any <b>nucleotide an</b> was carried out on the basis of the contained in the internatio	d/or amino acid sequence de sequence listing: nal application in written form.		ternational applicatio	n, the international search	
	rnational application in compu	ter readable form	<b>.</b>		
	this Authority in written form. this Authority in computer rea	dhle form			
	sequently furnished written se		es not go beyond the	e disclosure in the	
the statement that the info furnished	rmation recorded in computer	readable form is	identical to the writte	en sequence listing has been	
2. Certain claims were four	nd unsearchable (See Box I).				
3. Unity of invention is lack	king (see Box II).		•		
4. With regard to the title,					
X the text is approved as sul	bmitted by the applicant.				
the text has been establish	ned by this Authority to read a	s follows:			
5. With regard to the abstract,					
the text is approved as sult the text has been establish within one month from the	omitted by the applicant. ned, according to Rule 38.2(b) date of mailing of this internat	, by this Authority tional search repo	as it appears in Boort, submit comments	till. The applicant may, s to this Authority.	
6. The figure of the <b>drawings</b> to be publi	shed with the abstract is Figur	e No.		·	
as suggested by the applic			X	None of the figures.	
because the applicant fails  because this figure better	ed to suggest a figure.  characterizes the invention.				
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Form PCT/ISA/210 (first sheet) (July 1998)

### INTERNATIONAL SEARCH REPORT



A. CLASSIFICATION OF SUBJECT MATTER IPC 7 C07D471/04 A61K A61K31/4709 A61P31/00 //(C07D471/04,221:00, 209:00) According to International Patent Classification (IPC) or to both national classification and IPC **B. FIELDS SEARCHED** Minimum documentation searched (classification system followed by classification symbols) IPC 7 CO7D A61K A61P Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal, WPI Data, CHEM ABS Data C. DOCUMENTS CONSIDERED TO BE RELEVANT Category 9 Citation of document, with indication, where appropriate, of the relevant passages Relevant to claim No. Α US 5 849 752 A (GRUNENBERG ET AL) 1 15 December 1998 (1998-12-15) cited in the application abstract Further documents are listed in the continuation of box C. Patent family members are listed in annex. Special categories of cited documents: \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the "A" document defining the general state of the art which is not considered to be of particular relevance invention earlier document but published on or after the international "X" document of particular relevance; the claimed invention filing date cannot be considered novel or cannot be considered to document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such docu-ments, such combination being obvious to a person skilled document referring to an oral disclosure, use, exhibition or other means document published prior to the international filing date but in the art. later than the priority date claimed "&" document member of the same patent family Date of the actual completion of the international search Date of mailing of the international search report 13 February 2004 23/02/2004 Name and mailing address of the ISA Authorized officer European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Alfaro Faus, I Fax: (+31-70) 340-3016

## INTENATIONAL SEARCH REPORT

mation on patent family members

rnational Application No T/IB 03/04845

Patent document		Publication	Patent family Publication		
cited in search report		date	_	member(s)	date
US 5849752	Α	15-12-1998	DE	19546249 A1	19-06-1997
			ΑT	221531 T	15-08-2002
			ΑU	708006 B2	29-07-1999
			ΑŲ	7421696 A	19-06-1997
			BG	62258 B1	30-06-1999
			BG	101043 A	30-04-1998
			BR	9605968 A	18-08-1998
			CA	2192418 A1	13-06-1997
			CN	1160052 A ,B	24-09-1997
			CZ	9603646 A3	16-07-1997
			DE	59609501 D1	05-09-2002
			DK	780390 T3	11-11-2002
			EE	9600201 A	16-06-1997
			EP	0780390 A1	25-06-1997
			ES	2179910 T3	01-02-2003
			HR	960558 A1	28-02-1998
			HU	9603428 A2	28-08-1997
			ID	22625 A	02-12-1999
			ΙL	119795 A	27-12-1998
		,	IN	185805 A1	05-05-2001
			JP	9169757 A	30-06-1997
			NO	965298 A	13-06-1997
			NZ	299905 A	24-09-1998
			PL	317415 A1	23-06-1997
			PT	780390 T	29-11-2002
•			RU	2162468 C2	27-01-2001
			SG	47201 A1	20-03-1998
			SI	780390 T1	31-10-2002
			SK	159196 A3	08-10-1997
			TR	970481 A2	21-06-1997
			TW	411340 B	11-11-2000
			ZA	9610405 A	23-06-1997